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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/640,316	04/11/97	R.M. RHOA	

EXAMINER
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HM217/111

ART UNIT	PAPER NUMBER
	13

DATE MAILED:

11/17/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 8/27/98 + 10/13/98

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 25 - 33 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 25 - 33 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 + 12

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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**DETAILED ACTION**

1. Claims 25-33 are pending in this application. Claims 1-24 were canceled by the response filed 8/27/98.
2. Applicant's arguments with respect to claims 1-4 and 7-9 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 25, 28, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsarev.

Claims 25 and 28 are drawn to a DNA molecule encoding from amino acid 112 to about amino acid 607. Claims 31-33 are drawn to expression vectors and host cells comprising those sequences and methods of producing the recombinant protein.

Tsarev (Tsarev et al. 1996 in Enterically Transmitted Hepatitis Viruses pp 373-383) is in a compilation of articles which were presented at a Symposium on the dates of October 16-17, 1995, which is the public availability date for this article. Tsarev discloses the recombinant

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production of a protein of ORF-2 which begins at amino acid 112, and ends at approximately amino acid 609. Tsarev discloses DNA molecules encoding this protein, vectors comprising the sequences, host cells comprising the vectors, and recombinant expression of the protein. This protein was shown to be highly antigenic in ELISA assays, and immunogenic in animal vaccine models.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 26, 27, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsarev, as applied to claims 25, 28 and 31-33 above.

Claims 26 and 29 are drawn to DNA molecules encoding amino acids 112 to 607 of the ORF-2 protein. Claims 27 and 30 are drawn to DNA molecules encoding amino acids 112-578 of the ORF-2 protein.

As set forth above, Tsarev (Tsarev et al. 1996 in Enterically Transmitted Hepatitis Viruses pp 373-383) is in a compilation of articles which were presented at a Symposium on the dates of October 16-17, 1995, which is the public availability date for this article. Tsarev discloses the recombinant production of a protein of ORF-2 which begins at amino acid 112, and ends at

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approximately amino acid 609. Tsarev discloses DNA molecules encoding this protein, vectors comprising the sequences, host cells comprising the vectors, and recombinant expression of the protein. Tsarev suggests that other post translation modifications may occur to the expressed protein(p378), which could include further C-terminal clipping. This protein was shown to be highly antigenic in ELISA assays, and immunogenic in animal vaccine models. Further testing and modification to or shortening of the expressed protein would have been routine optimization of the ORF-2 antigen for one of ordinary skill in the art at the time the invention was made, absent unexpected results, as one would have been motivated to obtain the most antigenic and immunogenic polypeptide for further use in vaccination and testing.

7. No claim is allowed.

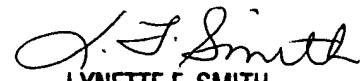
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz  
November 16, 1998

  
LYNETTE F. SMITH  
PRIMARY EXAMINER  
GROUP 1800